



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/644,333

08/20/2003

Bernd Disse

1/1196-1-C1

6665

28519

7590

11/30/2007

MICHAEL P. MORRIS

BOEHRINGER INGELHEIM CORPORATION

900 RIDGEBURY RD

P O BOX 368

RIDGEFIELD, CT 06877-0368

EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/644,333	Applicant(s) DISSE, BERND	
	Examiner Jagadishwar R. Samala	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,11-23 & 25-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,11-23 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1 Acknowledgement is made of amendment filed on 09/28/2007. Upon entering the amendment claims 1 and 11 are amended. Claims 10 and 24 are cancelled and the pending claims are 9, 11-23 and 25-32 and presented for examination.

Response to Arguments

2. Applicant's arguments filed on 09/28/2007 with respect to claims under 35 USC 102(e) has been fully considered but they are not persuasive. In view of the amendments to claims 9 and 11, 112(2) rejection is withdrawn. The 102(e) rejection of Pairet et al. (US 2002/0122773) is maintained and made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21 (2) of such treaty in the English language.

4. Claims 9, 11-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Pairet et al(US 2002/0122773).

The claims are drawn to a method for treating the inflammatory component of a disease such as cystic fibrosis using an effective amount of a tiotropium salt(e.g: bromide or methanesulphonate) Via inhalation:

Pairet et al(US'773, hereafter) teaches a treatment of respiratory tract diseases using tiotropium compound containing composition, see abstract. Especially, the teaching of US'773 relates to an inhaler (i.e., nebulizer) containing tiotropium salt (e.g, as counter-ion (anion) such as bromide or methanesulphonate, see paragraph 11).

Furthermore, the composition of US'773 is effectively treating an inflammatory diseases of respiratory tract including cystic fibrosis, see paragraph 30 at page 2.

As to claims 14 and 16-18, US'773 teaches inhalable powders and aerosols using propellant gas such as HFA134a, HFA227, TG134a, or TG227, see paragraphs 26 and 49.

As to claims 15 and 20-30, US'773 teaches excipients such as polyalcohols or polysaccharides at paragraph 42; other ingredients such as co-solvents, stabilizers, pH adjusters at paragraph 50; alcohol and glycol as co-solvents (paragraph at 57; pH of 2-7 at paragraph 55; and vitamins at paragraph 58, editic acid, sodium editate and benzakonium chloride at paragraphs 56 and 60; and so on.

All the critical elements are well taught by the cited reference and all the-claimed subject matter is clearly anticipated over the prior art of the record.

Applicants arguments filed on 09/28/2007 have been fully considered but they are not persuasive.

Applicant asserts that Pairet does not disclose and anticipate a method, which "comprises administering, via inhalation, a formulation comprising an active substance which consists of tiotropium salt and requires the additional dopamine agonist active substance.

This is not found persuasive because the claims recite the method comprises administering, via inhalation, a formulation "comprising" an active substance, and the term "comprising" is an open. Thus formulation comprising does not limit the presence of other active substances in combination with tiotropium salt. Therefore prior art teaches a formulation comprising of tiotropium salt as an active agent but also includes additional agents, which are not excluded from instant claim 9, which recites, "a formulation comprising". Furthermore, the composition disclosed by Pairet et al. is effectively treating an inflammatory diseases of respiratory tract including cystic fibrosis, to be used for the vary same purpose.

Conclusion

1. No claims are allowed at this time.
2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE MONTH** shortened statutory period, then the, shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
Primary Examiner
Art Unit 1618

